Subject: **Annual Report for Research Facilities** **Policy #17**

References: AWA Section 2143(a)(7)(A)
9 CFR, Part 2, Section 2.36

History: Replaces Policy #17 dated March 17, 1999. Provides requested guidance, deletes obsolete information related to the forms distribution process, and adds information regarding electronic submission of the annual report.

Justification: To further explain the Animal Welfare Act (AWA) and regulations regarding completion and submission of the "Annual Report of Research Facility" form.

Policy: As required by Section 2143 of the AWA and further explained in 9 CFR, Part 2, Section 2.36, each reporting research facility shall submit an annual report (APHIS Forms 7023 and 7023-A) to the Animal Care (AC) Regional office responsible for the State in which the facility is located. This report is due in the Regional office on or before **December 1** of each year.

These forms shall be signed and certified as correct by the Chief Executive Officer (CEO) or legally responsible Institutional Official (IO), and must include all species covered by the AWA **used** in research, tests, experiments, or for teaching and **being held for use** at the end of the U.S. Department of Agriculture's (USDA) fiscal year (FY) **(**October 1 through September 30). By signing the report, the CEO or IO is also certifying that the institution has adhered to the assurance statements at the bottom of the APHIS Form 7023.

Reporting of animals used (see forms) is based on the USDA FY (October 1 through September 30). Animals are to be counted only once, regardless of the number of proposals in which they were used. If an animal was used in more than one proposal, it must be counted in the most painful category. Animals used in multi-year studies will be counted once each fiscal year, regardless of when they were acquired.

Animals counted and listed in Column E must have a detailed statement explaining the procedure(s) and the basis for withholding pain-relieving medications.

Each research facility shall certify that the animal usage information submitted is true, correct and complete. It is recommended that every facility develop an animal accounting method sufficient to support this submission. USDA inspectors will verify the accuracy of these numbers during their inspection.

I. Distribution

On or before **September 15** of each year, the AC Regional office will send a packet via regular mail to the IO at each USDA registered and Federal research facility containing a notification letter, APHIS Form 7023, Column B and E explanation forms and other guidance documents, and instructions regarding the optional electronic submission process.

II. Instructions for Completing APHIS Forms 7023 and 7023-A

A. APHIS Forms

General instructions for completing the forms are included in the packet.

APHIS Form 7023: Items 1 through 3 completed by all facilities. Items 4 through 13 completed where applicable.

APHIS Form 7023-A (Continuation Sheet): Use only if needed to list additional species. Complete items 1, 2, 12, and/or 13.

B. Special Instructions for Column E

Entries in Column E must be explained in detail and attached to APHIS Form 7023. At a minimum, these statements should address the following:

1. A complete description of the procedure(s) producing pain and/or distress in the animal(s). For Federally mandated testing, this explanation should include, as appropriate, the name of the agency and specific reference citation from the Code of Federal Regulations or other relevant guidelines.
2. A complete explanation for withholding drugs for relieving pain and/or distress. For example, provide scientific justification that such drugs would adversely affect the test/study results, or cite all regulation(s) and/or Federal Agency policies that prohibit the use of these drugs.
3. An optional “Column E Explanation” form is included in the packet. Research facilities may find it useful to complete this form to provide the necessary information.

C. Exceptions to the Regulations and Standards

A summary of any Institutional Animal Care and Use Committee (IACUC) - approved exceptions to the regulations or standards must be submitted in hard copy to the appropriate Regional office. At a minimum, this summary should include the following:

1. Identify IACUC-approved exception(s) to the regulations or standards, including exemptions to the dog exercise plan and/or the nonhuman primate plan for environmental enhancement.

2. Describe the IACUC-approved exception(s).

3. Identify the species and number of animals affected.

D. Other Information

Column F contains only the total number of animals listed in Columns C, D and E. Do not include animals from Column B.

It is not necessary to report birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, or any other animals not defined as animal by 9 CFR, Part 1- Definitions of Terms, Section 1.1. This includes fish, amphibians and livestock or poultry used in agricultural research.

Wild rats and mice **are** covered and must be reported.

State the **common names** of the animals in Column A if they are not already listed.

"Other Farm Animals": List farm animals other than pigs and sheep such as goats, cattle, llamas, etc.

"Other Animals" refers to other covered animals (not farm animals). This would include, but not be limited to, animals such as gerbils, ferrets, seals, tigers, opossums, raccoons, wolves, and bobcats.

Incomplete forms or inaccurate data will be returned to the issuing facility at the discretion of the Regional office.

III. Routing of Completed APHIS Forms 7023 and 7023-A

Annual report forms from all facilities must be returned to the appropriate Regional office by **December 1** of each year. Enforcement action may be initiated if the reports are not submitted by this required deadline.

Facilities with multiple sites should collect and combine their annual reports into one report before submitting.

Electronic Submission

1. This system is only available on the USDA-APHIS-Animal Care website from **September 15** to **December 1** each year.
2. A password must be requested via e-mail by the CEO or IO, and will be mailed to them hard-copy from the appropriate Regional office. Information on how to obtain the password is included in the packet mailed to each institution in September.
3. Only animal numbers and species for each category, and Column E explanations may be entered. IACUC-exception information must be submitted in hard copy to the Regional office.

Original submissions of APHIS Forms 7023 and 7023-A will be retained by the Regional office.

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023

(Refer to 9 CFR Part 2, Subpart C, Section 2.33 and 2.36)

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA.

ITEM 3 - List Location of each Facility or Site where animals were housed or used in actual research, testing, teaching, or experimentation, or held for those purposes. *(Attached additional sheets if necessary.)*

ITEM 4 -13 - DO NOT enter numbers in Column A. **DO NOT** add numbers enterd in Column B into the total in Column F. **Column F** is to show total of numbers entered in Columns **C + D + E.** Entries in Column E must be explained on attached sheet(s).

ITEM 12 - List by common name all other farm animal species.

ITEM 13 - Other: List, by common name, all other warm blooded animal species covered by the Regulations. *(This will include all wild or exotic species.)* Attach additional sheets if necessary or use APHIS Form 7023A.

CERTIFICATIONS: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on the behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE REGIONAL OFFICE.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. **CUSTOMER NO.**

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS **(Cols. C + D + E)**
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. **CUSTOMER NO.**

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	**F.** TOTAL NO. OF ANIMALS **(Cols. C + D + E)**

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL** *(Type or Print)*	**DATE SIGNED**